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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,173

04/19/2005

Glenn D. Prestwich

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,173	<b>Applicant(s)</b> PRESTWICH ET AL.	
	<b>Examiner</b> DAVID LUKTON	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 10-12 and 15-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 7-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Pursuant to the directives of the response filed 12/31/07, claim 1 has been amended. Claims 1-115 remain pending. Claims 1-3, 7-9, 13, 14 are examined in this Office action; claims 4-6, 10-12, 15-115 remain withdrawn from consideration.

Applicants' arguments filed 12/31/07 have been considered and found not persuasive. In this Office action, claims 1-3, 13, 14 are rejected, and claims 7-9 are objected to because of their dependence on rejected claims.



Claim 2 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is not properly subgeneric to claim 1. Claim 1 excludes the possibility that "Y" can be an unspecified "pharmaceutically acceptable compound". However, this is permitted by claim 2. One option would be to cast claim 2 in independent form.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3, 13, 14 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103 as obvious over Roy, Rene (*Carbohydrate Letters* 2(4), 259-266, 1997).

Roy discloses compound 9 on page 261. Claim 1 encompasses this when the substituent variables are as follows:

Y = a polysaccharide

L = a polyalkylene group (i.e., ethylene)

Q = sulfhydryl.

Thus, the claims are anticipated, or rendered obvious.

▲

The following is a quotation of 35 USC, §103 which forms the basis for all obviousness rejections set forth in the Office action:

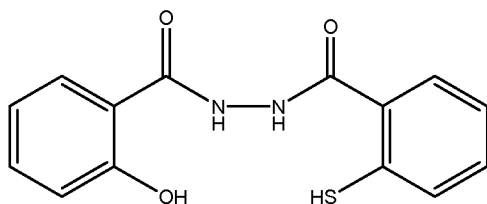
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 2 is rejected under 35 U.S.C. §103 as being unpatentable over Zhao (*J Med Chem* **40**, 937-941, 1997).

Zhao discloses (page 939) the following compound:



This anticipates claim 1 when the substituent variables are as follows:

Y = phenol

L = -C<sub>6</sub>H<sub>4</sub>-

Q = -SH

In response, applicants have argued that claim 2 excludes the possibility that “Y” can be any compound which applicants might regard as “pharmaceutically acceptable”. However, applicants are not correct. It is suggested that applicants reconsider the language of claim 2.

. . . . .

Claim 2 is rejected under 35 U.S.C. §103 as being unpatentable over Young (USP 4,767,745).

Young discloses compound VIII at cols 7-8 (second-to-last structure). This is encompassed by claim 1 when the variables are as follows:

Y = leukotriene ;

L = polyalkylene

Q = maleimide.



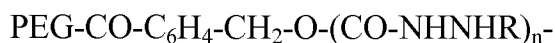
Claims 1-3 are rejected under 35 U.S.C. §103 as being unpatentable over Janda (USP 6,664,372).

As indicated previously, Janda discloses (col 4, lines 51-57) a compound which contains the requisite dicarbonyl hydrazine group. At one terminus of the compound there is a variable “Rx”; it is recited at col 4, line 62 that this Rx group can be the side chain of cysteine. The claims are rendered obvious for the case of “Y” being a synthetic copolymer, and “L” being a polyimino group. (Note that hydrazine itself would qualify as a polyimino group, since “poly” includes the number 2, according to applicants).

In response to the foregoing, applicants have pointed to substituent variable “Y”, which can be a “synthetic polymer”, and have argued that because the claim does not recite that the polymer **is** a hydrazide, it therefore follows that hydrazides are excluded. However, applicants’ interpretation of claim 1 is unjustifiably narrow.

Or it may be the case that applicants are not familiar with polymer terminology.

Consider the following group:



This could easily qualify as a “block copolymer”. There is a vast quantity of literature on this. By way of example, applicants might take a look at the following US Patents: 7332542, 7323528, 7316811, 7311901, 5705194, 5683723, 5665831, & 5618528. The ‘528 patent (Cooper), for example, discloses linear block copolymers that contain alkylene oxide units and peptide units. A polymer chemist of ordinary skill would not argue that a copolymer fails to qualify as a polymer. Turning back to the compound in Janda, an oligomer of hydrazine  $[(-\text{CO}-\text{NHNHR}-)_n]$  would qualify as a polymer, even for the case of “n” being just two. This conclusion (for  $n=2$ ) is reached because applicants regard ethylene as being a “poly” alkyl group. (In applicants lexicon, the prefix “poly” includes the integer 2). In any case, the Janda compound qualifies as a block copolymer, and as indicated a block copolymer is a kind of “synthetic polymer”.

Accordingly, the rejection is maintained.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

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PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/  
Primary Examiner, Art Unit 1654